



May 9, 2024

Optos Plc
Graham Mcleod
Senior Director of Regulatory Affairs
Queensferry House, Carnegie Campus
Enterprise Way
Dunfermline, Fife KY11 8GR
United Kingdom

Re: K233602
Trade/Device Name: P200te (a10700)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, MYC
Dated: March 28, 2024
Received: March 29, 2024

Dear Graham Mcleod:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K233602

Device Name

P200TE (A10700)

Indications for Use (Describe)

The P200TE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer. It is intended for in-vivo viewing, digital imaging, and measurement of posterior ocular structures, including the retina, retinal nerve fiber layer, ganglion cell complex (GCC) and optic disc under mydriatic and nonmydriatic conditions.

P200TE is indicated for producing high resolution, ultra-widefield, en face reflectance images, autofluorescence images, axial cross-sectional images, three-dimensional images, retinal layer boundary analysis, optic nerve head analysis and thickness maps.

The P200TE includes a Reference Database that enables the results of OCT segmentation analysis to be compared to reference data, including Full retinal thickness, Ganglion Cell Complex thickness, Retina Nerve Fiber Layer thickness and Optic Nerve Head metrics.

The P200TE is indicated for use as a device to aid in the detection, diagnosis, documentation and management of retinal health and diseases that manifest in the retina.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Contact Details

Applicant	Optos Plc Queensferry House Carnegie Campus Enterprise Way Dunfermline, Fife Scotland, UK KY11 8GR
Primary Correspondent	Graham McLeod Sr. Director of Regulatory Affairs, Optos Plc Tel: 0044 1383 843300 E-mail: RA@optos.com (preferred)
Secondary Correspondent	Rachel Reay Sr. Regulatory Specialist, Optos Plc Tel: 0044 1383 843300 E-mail: RA@optos.com (preferred)
Date Prepared	25th March 2024

2. Subject Device

Device Trade Name	P200TE (A10700)
Common Name	Ophthalmoscope
Classification	Tomography, Optical Coherence
Regulatory Class	886.1570
Product Code	OBO, MYC

3. Legally Marketed Predicate Devices

Predicate #	K121739 (Primary)	K231673
Device Trade Name	iVue	P200TE (A10700)
Product Code	OBO, HLI	OBO, MYC

4. Device Description

The P200TE is a desktop retinal imaging device that can perform ultra-widefield scanning laser ophthalmoscopy and optical coherence tomography. Ultra-widefield images can be captured in less than half a second. The device is intended to be used by ophthalmic and optometry health care professionals.

The P200TE delivers images in the following image modes:

- Scanning Laser Ophthalmoscopy
- Reflectance imaging
- Autofluorescence imaging
- Optical Coherence Tomography

The P200TE instrument uses red and green laser illumination for reflectance imaging, enabling it to image pathology throughout the layers of the retina, from the sensory retina and nerve fiber layer, through the retinal pigment epithelium (RPE) and down to the choroid. The image can be separated to present the distinct retinal sub-structures associated with the individual imaging wavelengths.

The P200TE instrument uses green laser illumination to excite autofluorescence (AF) emission from the naturally occurring lipofuscin in the fundus.

The P200TE instrument uses a broadband near-infrared (N-IR) super-luminescent diode (SLD) light source for optical coherence tomography allowing a depth profile of the reflectance of the fundus to be recorded. The P200TE instrument uses N-IR laser illumination for reflectance imaging simultaneously with OCT imaging. Reflectance images are used to track eye position during OCT imaging and are not available to the user.

The P200TE images the eye via two ellipsoidal mirrors arranged so that a focal point of one of the mirrors coincides with a focal point of the other mirror; a mirrored scanner is also located at this common focal point. The pupil of the subject's eye is placed at one of the other focal points. A second mirrored scanner is located at the remaining focal point; a laser or SLD reflected off this scanner is relayed onto the second scanner by the first ellipsoidal mirror and from there is reflected through the pupil and into the eye by the second ellipsoidal mirror. The second scanning element is different for OCT and SLO imaging. The energy reflected back from the retina, or emitted by fluorophores, returns through the same path to the detectors; the images are generated from the captured detector data.

P200TE OCT images are automatically segmented to identify and annotate retinal layers and structures, enabling practitioners to efficiently assess retinal structures in support of detecting, monitoring and documentation. A Reference Database enables the automatic annotation of OCT segmentation results to provide comparison to a known healthy population. Segmentation outcomes are recorded as annotations and support adjustment as deemed necessary by the clinician.

P200TE automatic segmentation provides comprehensive retinal and optic nerve head information, including:

- Full Retinal Thickness (FRT)
- Ganglion Cell Complex Thickness (GCC)
- ONH Analysis
- ONH Nerve Fiber Layer Thickness

The P200TE refers to the scan head component of the system, together with touchscreen and hand controller. The device is supported by an image server which delivers patient management and image storage, as well as interfacing with the business systems and Electronic Medical Record systems.

The images are captured by the scan head under operator control and then automatically saved to the image server that uses a database structure to hold the images and patient information. For subsequent image review, a number of viewing PCs are connected remotely or via a local area network to the image server. The patient records and images are then accessible in a distributed format suited to the physical layout of the eye-care practice.

Images can be reviewed through OptosAdvance review software (K162039) either on the image server, or on individual review stations, or other compatible PACS viewers.

5. Indications for Use

The P200TE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer. It is intended for in vivo viewing, digital imaging, and measurement of posterior ocular structures, including the retina, retinal nerve fiber layer, ganglion cell complex (GCC) and optic disc under mydriatic and non-mydriatic conditions.

P200TE is indicated for producing high resolution, ultra-widefield, en face reflectance images, autofluorescence images, axial cross-sectional images, three-dimensional images, retinal layer boundary analysis, optic nerve head analysis and thickness maps.

The P200TE includes a Reference Database that enables the results of OCT segmentation analysis to be compared to reference data, including Full retinal thickness, Ganglion Cell Complex thickness, Retina Nerve Fiber Layer thickness and Optic Nerve Head metrics.

The P200TE is indicated for use as a device to aid in the detection, diagnosis, documentation and management of retinal health and diseases that manifest in the retina.

6. Substantial Equivalence to Predicate

Both P200TE and iVue are Spectral Domain optical coherence tomographers intended for in-vivo digital imaging of posterior ocular structures, with retinal layer boundary analysis, optic nerve head analysis and thickness maps. Both devices provide a reference database to allow comparison of measurements against a database of known subjects.

The updated P200TE has all the same indications for use as P200TE and alongside this introduces the opportunity for comparison to a reference database, present in the primary predicate device, iVue. In other words, the P200TE has the same intended use as its predicate devices, and thus satisfies the first criterion for a finding of substantial equivalence.

The Optos Reference Database (RDB) enables the automatic annotation of OCT segmentation results to provide comparison to a known healthy population cohort of 860 subjects across an age range 22-84 years, with an average age of 51. This is shown in terms of percentiles. Cut-off values of 1%, 5%, 95%, and 99% (determined with a non-parametric method) are used to color-code results to indicate where they fall in relation to database distribution. This is similar to iVue, which uses color-coded percentile categories to denote 'within normal', 'borderline', or 'outside normal' based on cut-off levels of 5% for 'borderline' and 1% for 'outside normal'.

The Optos RDB is partitioned into three strata, based on optic disc size as the prioritized covariate for RNFL and ONH RDB comparisons. It is non-parametric, with an age profile intended to mirror disease prevalence. These covariates are selected in line with the parameters used in the predicate iVue database.

Technological implementation of SLO and OCT imaging is identical between the cleared P200TE and this submission of the P200TE with RDB. No technological updates are included in this submission.

P200TE with segmentation and RDB is substantially equivalent to the previously cleared P200TE (K231673), and RDB functionality is also substantially equivalent to the Optovue iVue (K121739). Minor differences in RDB implementation do not present different questions of safety or effectiveness than the predicate device because there are no novel technological principles or applications introduced.

Table 1: Substantial Equivalence Chart

Device	OPTOS P200TE with segmentation and RDB	Optovue iVue	OPTOS P200TE with segmentation
510(k) Number	K233602	K121739 (Primary predicate)	K231673
Indications For Use	<p>The P200TE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer. It is intended for in vivo viewing, digital imaging, and measurement of posterior ocular structures, including the retina, retinal nerve fiber layer, ganglion cell complex (GCC) and optic disc under mydriatic and non-mydriatic conditions.</p> <p>P200TE is indicated for producing high resolution, ultra-widefield, en face reflectance images, autofluorescence images, axial cross-sectional images, three-dimensional images, retinal layer boundary analysis, optic nerve head analysis and thickness maps.</p> <p>The P200TE includes a Reference Database that enables the results of OCT segmentation analysis to be compared to reference data, including Full retinal thickness, Ganglion Cell Complex thickness, Retina Nerve Fiber Layer thickness and Optic Nerve Head metrics.</p> <p>The P200TE is indicated for use as a device to aid in the detection, diagnosis, documentation and management of retinal health and diseases that manifest in the retina.</p>	<p>The iVue is a non-contact, high resolution tomographic imaging device. It is intended for in vivo imaging, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including retina, retinal nerve fiber layer, ganglion cell complex (GCC), optic disc, cornea, and anterior chamber of the eye. The iVue with Normative Database is a quantitative tool for the comparison of retina, retinal nerve fiber layer, ganglion cell complex, and optic disc measurements to a database of known normal subjects.</p> <p>The iVue with Normative Database is indicated for use as a device to aid in the diagnosis, documentation, and management of ocular health and diseases in the adult population.</p>	<p>The P200TE is a non-contact scanning laser ophthalmoscope and optical coherence tomographer. It is intended for in-vivo viewing, digital imaging, and analysis of posterior ocular structures, including the retina, retinal nerve fiber layer, ganglion cell complex (GCC) and optic disc, under mydriatic and non-mydriatic conditions.</p> <p>It is indicated for producing high resolution, ultra-widefield, en face reflectance images, autofluorescence images, axial cross-sectional images, three-dimensional images, retinal layer boundary analysis, optic nerve head analysis and thickness maps.</p> <p>The P200TE is indicated for use as a device to aid in the detection, diagnosis, documentation and management of retinal health and diseases that manifest in the retina.</p>
Product Code	MYC, OBO	HLI, OBO	MYC, OBO
Regulation Number	21 CFR 886.1570	21 CFR 886.1570	21 CFR 886.1570
Device Classification	II	II	II
Components	Scanhead Headrest and chinrest Powered Table (separate) Computer	Scanner Computer Control box Footswitch (optional) Joystick and chinrest	Scanhead Headrest and chinrest Powered Table (separate) Computer

		assembly	
SLO Technology Characteristics			
Light Source	Laser	N/A	Laser
Wavelength and Color of Light	532nm \pm 5nm: green 635nm \pm 5nm: red	N/A	532nm \pm 5nm: green 635nm \pm 5nm: red
Laser Class	Class 1 to ISO 60825	N/A	Class 1 to ISO 60825
Number of lasers used per Scan	1 or 2	N/A	1 or 2
External Field of View	120°	N/A	120°
Internal Field of View	200°	N/A	200°
Wide Angle Digitized Image Size	3900x3072 pixels	N/A	3900x3072 pixels
Scan Patterns	2 axis scanner	N/A	2 axis scanner
Software	Embedded and Application	N/A	Embedded and Application
OCT Technology Characteristics			
Method of Operation	Spectral Domain OCT	Spectral Domain OCT	Spectral Domain OCT
Light Source	SLD 830-850nm Super Luminescent Diode Nominal center wavelength 840nm 50nm FWHM bandwidth 782nm \pm 3nm: infra-red	SLD 830 nm to 850 nm Super Luminescent Diode	SLD 830-850nm Super Luminescent Diode Nominal center wavelength 840nm 50nm FWHM bandwidth 782nm \pm 3nm: infra-red
Scan Rate	70,000 A-scans/s	25,000 A-Scans/s	70,000 A-scans/s
Scanner Type	Galvanometric mirror pair	Lens based system	Galvanometric mirror pair
Light Source Classification	Class 1	Class 1	Class 1
Transverse Resolution	20 μ m	15 μ m	20 μ m
Axial Resolution	< 7 μ m	5 μ m	< 7 μ m
Transverse scan range	5.28 mm to 12 mm	2 mm to 12 mm	5.28 mm to 12 mm
Scan Patterns	Line Volume Circle	Line Volume Circle	Line Volume Circle
Depth Range (in tissue)	2.3mm	2.3mm	2.3mm
Acquisition time	\leq 2s	\leq 2s	\leq 2s
Retinal Tracking	Yes	No	Yes

Ergonomics	Tabletop Scanner Headrest and Chinrest Touchscreen & Hand controller	Tabletop Scanner Computer Control box Footswitch (optional) Joystick and chinrest assembly	Tabletop Scanner Headrest and Chinrest Touchscreen & Hand controller
Cleaning and disinfection / sterilization	Sterilization not required. Clean/ disinfect contact points	Sterilization not required. Clean/ disinfect contact points	Sterilization not required. Clean/ disinfect contact points
Safety Features	Laser & SLD shutdown on light source overpower and/or incorrect functioning of scanning elements	Halt to operation for status abnormality	Laser & SLD shutdown on light source overpower and/or incorrect functioning of scanning elements
Software	Embedded and Application	Embedded and Application	Embedded and Application
Operating System	Linux (SLO) Windows (Application & OCT)	32 or 64 bit Windows XP Pro. Ed./Win 7	Linux (SLO) Windows (Application & OCT)
OCT Analysis			
Retinal Thickness			
<i>Full Retinal Thickness</i>	9 sector ETDRS	9 sector ETDRS	9 sector ETDRS
<i>GCC Thickness</i>	Averaged; Fovea-centered Hemifields	Averaged; Temporally Offset Hemifields	Averaged; Fovea-centered Hemifields
Optic Disc Analysis			
<i>RNFL peripapillary</i>	Averaged, Quads, TSNIT	Averaged, quads, TSNIT	Averaged, Quads, TSNIT
<i>Disc area</i>	Yes	Yes	Yes
<i>Rim area</i>	Yes – reference plane model	Yes – fixed offset model	Yes – reference plane model
<i>C/D area</i>	Yes	Yes	Yes
<i>C/D horizontal ratio</i>	Yes	Yes	Yes
<i>C/D vertical ratio</i>	Yes	Yes	Yes
OCT Reference Database			
Method	Non-Parametric based reference database	Regression based normative database	N/A
Cohort	860 subjects, age range 22-84 years	458 subjects, age range 18-82 years	N/A
RDB Presentation Scheme	Cut-off values of 1%, 5%, 95%, and 99% are used to color-code results	Cut-off values of 1%, 5%, 95%, and 99% are used to color-code results	N/A

Table 2: The physical principles of operation for each modality, consistent with the predicate device P200TE

Modality	Imaging mode	Physical principle	Output	Use scenario
Reflectance imaging (SLO)	Optomap UWF composite Red / Green retinal imaging Optomap/Optomap plus resolution modes	Point by point mapping of reflected light intensity from multi-channel laser incident on retina.	2D image of the retina.	To enable UWF visualization and quantitative assessment of the retina, choroid, optic nerve head and nerve fiber layer when viewed in a compatible DICOM viewer.
Fluorescence imaging (SLO)	Optomap UWF Auto-Fluorescence (AF) imaging Optomap/Optomap plus resolution modes	Point by point mapping of fluorescence light intensity from multi-channel laser incident on retina.	2D image of the retina. AF relies on natural fluorophores present in retina.	To enable UWF visualization and quantitative assessment of the health of the cells when viewed in a compatible DICOM viewer. Areas of Hypo and Hyper fluorescence are used by practitioners to assess the metabolism of the eye.
Optical Coherence Tomography (OCT)	Central Posterior OCT Imaging	Point by point mapping of back-scattered light intensity, resolved in the axial direction through coherence gating. Coherence gating is achieved through low-coherence interferometry. Low coherence light is incident on the retina for axial mapping.	2D axial cross section (B-scan) or 3D volume (C-scan) of retina. Provides structural information of retina in the axial and transverse direction	To support investigation of anomalies found in the SLO RG or AF, and to broadly assess the health at the Macula and through the ONH. Providing 3D structural information in the macular and ONH regions, through single scans or a combination of scans. For use in conjunction with Red-Green and Auto Fluorescence SLO images to assess eye health

7. Summary of Studies

Non-Clinical Performance Testing

Technological implementation of SLO and OCT imaging is identical between the cleared P200TE and the submitted P200TE with RDB. No technological updates are included in this submission.

Non-clinical system testing provided an evaluation of the performance of the system relevant to each of the system specifications. The functional and system level testing showed that the system met the defined specifications, with no concerns raised in relation to key non-functional performance parameters.

Design Verification and Validation of the A10700 P200TE with RDB has been performed in support of this submission, including OCT non-functional performance parameters and functional parameters for the US Reference Database.

The P200TE is type tested in accordance with the following standards:

- IEC 60601-1:2015+A11:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment – Part 1.2: General requirements for safety – collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60825-1:2007 Safety of laser products - Part 1: Equipment classification and requirements

Safety Calculations are also provided with reference to ANSI Z80.36-2021 Ophthalmics - Light Hazard Protection for Ophthalmic Instruments.

Sterility, Shelf-Life, Biocompatibility and Animal Testing was not required for this submission.

Software verification and validation has been conducted in accordance with QMS processes and documentation has been provided with this submission.

All testing has passed with no additional safety or performance concerns raised.

Clinical Performance Testing

A reference database of healthy eyes was created for measurement comparisons in order to flag parameters that fall outside the normal range. Standard cut-off values were chosen including the 1%, 5%, 95%, and 99% levels. Measurements within the 5-95% are considered 'within normal limits' and colored green for easy interpretation.

- **RNFL, GCC, and ONH Rim measurements:** Values below the 5% are considered 'borderline' and colored amber for easy interpretation, and values below the 1% are considered 'outside normal limits' and colored red.
- **ONH C/D parameters:** Values above the 95% level are colored amber and values above the 99% level are colored red.
- **FRT measurements:** Values below 5% are colored light blue and values below 1% are colored dark blue while values above the 95% level are colored amber and values above the 99% level are colored red.

The cut-off values were determined using a non-parametric analysis to reduce potential bias introduced when using standard parametric techniques due to their underlying assumptions. The reference database was split into 3 divisions for RNFL and ONH measurements based on optic disc size. The small, medium, and large optic disc groups were used to take into account the influence of disc size on these measurements.

In total, 879 eyes were enrolled in the study. For full retina thickness and GCC measurements, the final number included in the analysis was 860 eyes. The RNFL and ONH measurements were divided into three groups based on disc size (due to the large effect of optic disc size on these measurements). For eyes with small optic discs (disc area < 1.76 mm²), the final number included in the RNFL analysis was 279, and the final number in the ONH analysis was 284. For eyes with medium optic discs (disc area between 1.76 mm² and 2.15 mm²), the final number included in the RNFL analysis was 320, and the final number in the ONH analysis was 321. For eyes with large optic discs (disc area > 2.15 mm²), the final number included in the RNFL analysis was 254, and the final number in the ONH analysis was 255.

The age distribution was skewed toward older eyes with the mean age in the database of 51 years old with 56% of eyes over the age of 50. There was good racial and ethnic diversity with 15% of patients Hispanic, 16% Asian, 14% Black or African American, and 57% White. The age distribution was intentionally skewed toward older eyes in order to better match the age distribution typically found in eye clinics and representing eyes susceptible to age-related eye diseases. Because of this, age-related corrections were not necessary for this database.

These data were analyzed with a non-parametric method to determine the 1%, 5%, 95%, and 99% cut off values, with no overlap between intervals at 90% confidence. These values were implemented into software for the device that alerts users when measurement values fall outside these cut-off limits. In this way, the reference database aids in the detection and management of ocular disease.

OPT1089 Summary Tables

Table 3: Study demographic information

Baseline Characteristic	Statistic	Value
Age at Enrolment	N (population size)	879
	n (non-missing sample size)	879
	Mean	51.0
	Standard Deviation	15.39
	Median	53
	Minimum	22
	Maximum	84
Age Group N (%)	22-30	124 (14.1)
	31-40	97 (11.0)
	41-50	165 (18.8)
	51-60	232 (26.4)
	61-70	177 (20.1)
	71+	84 (9.6)
Sex N (%)	Female	543 (61.8)
	Male	335 (38.1)
	Unspecified	1 (0.1)
Ethnicity N (%)	Hispanic or Latino	128 (14.6)
	Non Hispanic or Latino	751 (85.4)
Race N (%)	American Indian / Alaska Native	1 (0.1)
	Asian	144 (16.4)
	Black or African American	122 (13.9)
	Native Hawaiian or Other Pacific Islander	11 (1.3)
	White	501 (57.0)
	Other	100 (11.4)

Table 4: Summary statistics and cut-off percentiles for Full Retinal Thickness measurements

Parameter	N (population size)	n (non-missing sample size)	Mean (95% CI of Mean)	Standard Deviation	Median (Min, Max)	Percentiles and 90% CIs			
						1st percentile	5th percentile	95th percentile	99th percentile
Central Foveal Thickness	879	860	247.04 (245.55, 248.52)	22.160	246.23 (183.82, 329.70)	195.74 (189.60, 199.07)	212.32 (208.39, 214.15)	283.34 (280.22, 288.51)	302.84 (300.76, 310.93)
Superior Parafoveal Thickness	879	860	315.00 (314.00, 316.00)	14.998	314.81 (254.21, 361.60)	278.64 (277.01, 281.13)	290.54 (287.38, 292.30)	339.33 (337.97, 340.78)	351.57 (347.65, 354.03)
Temporal Parafoveal Thickness	879	860	303.45 (302.47, 304.42)	14.585	303.28 (249.22, 350.19)	269.57 (262.19, 271.14)	279.39 (277.69, 280.71)	326.82 (324.75, 329.39)	338.66 (334.77, 341.17)
Inferior Parafoveal Thickness	879	860	312.35 (311.35, 313.34)	14.814	312.28 (253.75, 359.73)	278.01 (271.74, 280.86)	287.24 (285.59, 288.11)	335.93 (334.38, 337.52)	348.59 (344.55, 351.81)
Nasal Parafoveal Thickness	879	860	316.55 (315.49, 317.61)	15.815	316.97 (257.44, 364.37)	277.99 (272.89, 282.46)	289.85 (287.75, 292.50)	342.07 (340.34, 344.30)	354.37 (350.10, 358.87)
Superior Perifoveal Thickness	879	860	278.54 (277.62, 279.46)	13.717	278.64 (227.52, 322.60)	244.80 (239.81, 248.65)	256.88 (255.46, 258.57)	300.63 (299.57, 303.68)	313.65 (308.92, 317.20)
Temporal Perifoveal Thickness	879	860	260.50 (259.64, 261.35)	12.789	260.27 (214.64, 304.00)	230.24 (222.82, 235.42)	240.19 (238.76, 241.71)	281.03 (279.55, 283.25)	290.68 (288.88, 292.21)
Inferior Perifoveal Thickness	879	860	265.08 (264.18, 265.98)	13.447	265.12 (217.70, 308.01)	234.08 (229.50, 236.15)	241.98 (241.20, 243.29)	286.98 (285.67, 289.82)	297.36 (294.27, 299.26)
Nasal Perifoveal Thickness	879	860	291.78 (290.78, 292.78)	14.983	291.67 (234.72, 345.70)	255.73 (252.18, 259.22)	267.25 (265.56, 268.74)	316.25 (315.08, 317.63)	328.19 (326.46, 335.06)

Table 5: Summary statistics and cut-off percentiles for GCC thickness measurements

Parameter	N (population size)	n (non-missing sample size)	Mean (95% CI of Mean)	Standard Deviation	Median (Min, Max)	Percentiles and 90% CIs			
						1st percentile	5th percentile	95th percentile	99th percentile
Total Average	879	860	108.03 (107.53, 108.53)	7.480	107.95 (82.67, 132.46)	88.01 (86.66, 90.71)	95.31 (93.67, 96.07)	120.45 (119.77, 121.24)	124.09 (122.74, 126.80)
Superior Hemiretina	879	860	107.90 (107.39, 108.40)	7.539	107.81 (83.65, 133.04)	87.88 (85.93, 91.01)	95.65 (94.26, 96.48)	120.09 (119.04, 120.97)	124.37 (123.63, 126.71)
Inferior Hemiretina	879	860	108.16 (107.62, 108.69)	8.003	108.16 (79.83, 131.87)	87.22 (84.41, 89.91)	94.20 (93.29, 95.26)	121.44 (120.54, 122.10)	125.07 (124.30, 125.55)

Table 6: Summary statistics and cut-off percentiles for RNFL measurements

Parameter	Optic Disc Size	N (population size)	n (non-missing sample size)	Mean (95% CI of Mean)	Standard Deviation	Median (Min, Max)	Percentiles and 90% CIs			
							1st percentile	5th percentile	95th percentile	99th percentile
Average RNFL Thickness Over TSNIT Circle	Small optic disc	879	279	106.46 (105.17, 107.74)	10.892	106.39 (69.03, 133.00)	80.21 (69.03, 84.23)	88.75 (84.82, 90.29)	123.69 (122.12, 127.36)	131.50 (129.16, 133.00)
	Medium optic disc	879	320	112.02 (110.82, 113.22)	10.905	112.49 (76.48, 150.30)	85.95 (76.48, 89.31)	95.04 (90.46, 96.57)	129.77 (126.84, 135.14)	138.91 (136.22, 150.30)
	Large optic disc	879	254	113.85 (112.39, 115.30)	11.802	113.90 (81.54, 147.45)	84.94 (81.54, 91.80)	94.69 (92.26, 96.93)	134.91 (130.76, 137.14)	141.23 (138.05, 147.45)
Temporal Quadrant RNFL Over TSNIT Circle	Small optic disc	879	279	86.02 (84.44, 87.61)	13.458	84.08 (58.57, 140.45)	60.43 (58.57, 65.23)	68.10 (65.62, 69.06)	110.48 (107.24, 115.73)	125.88 (117.33, 140.45)
	Medium optic disc	879	320	84.36 (83.11, 85.60)	11.325	83.79 (58.32, 122.78)	62.77 (58.32, 63.83)	67.70 (64.56, 69.64)	103.36 (102.25, 105.96)	112.17 (109.71, 122.78)
	Large optic disc	879	254	85.05 (83.68, 86.43)	11.095	83.14 (63.77, 121.46)	64.13 (63.77, 66.04)	69.33 (66.06, 71.12)	105.56 (101.74, 108.42)	114.64 (108.49, 121.46)
Superior Quadrant RNFL Over TSNIT Circle	Small optic disc	879	279	123.65 (121.46, 125.83)	18.546	124.75 (70.59, 194.77)	76.32 (70.59, 86.63)	93.78 (87.35, 96.73)	154.85 (148.94, 160.52)	169.49 (161.46, 194.77)
	Medium optic disc	879	320	133.10 (131.25, 134.95)	16.802	133.63 (75.20, 191.32)	88.47 (75.20, 92.06)	106.40 (98.23, 110.09)	160.02 (156.25, 167.04)	175.92 (167.98, 191.32)
	Large optic disc	879	254	134.30 (132.13, 136.47)	17.534	133.70 (89.95, 180.56)	98.81 (89.95, 101.16)	104.19 (101.29, 109.02)	165.15 (161.79, 170.74)	175.46 (171.56, 180.56)
Inferior Quadrant RNFL Over TSNIT Circle	Small optic disc	879	279	133.68 (131.54, 135.82)	18.168	135.09 (57.76, 178.33)	78.52 (57.76, 96.86)	103.68 (97.59, 107.12)	162.16 (158.33, 171.79)	175.59 (171.81, 178.33)
	Medium optic disc	879	320	141.73 (139.84, 143.63)	17.204	142.58 (90.98, 206.53)	97.91 (90.98, 101.85)	112.68 (106.12, 116.40)	168.23 (164.27, 176.26)	185.34 (180.42, 206.53)
	Large optic disc	879	254	145.48 (143.15, 147.82)	18.907	145.37 (88.95, 198.32)	98.84 (88.95, 110.16)	113.91 (111.74, 118.11)	178.58 (171.76, 181.11)	190.48 (181.34, 198.32)
Nasal Quadrant RNFL Over TSNIT Circle	Small optic disc	879	279	82.49 (80.73, 84.26)	14.963	80.54 (46.51, 128.37)	51.13 (46.51, 57.55)	59.61 (58.03, 61.95)	109.27 (103.97, 116.10)	124.93 (116.37, 128.37)

Table 7: Summary statistics and cut-off percentiles for ONH measurements

Parameter	Optic Disc Size	N (population size)	n (non-missing sample size)	Mean (95% CI of Mean)	Standard Deviation	Median (Min, Max)	Percentiles and 90% CIs			
							1st percentile	5th percentile	95th percentile	99th percentile
ONH: C/D Vertical	Small optic disc	879	284	0.376 (0.353, 0.399)	0.1981	0.409 (0.000, 0.773)	0.000 (0.000, 0.000)	0.000 (0.000, 0.000)	0.648 (0.616, 0.683)	0.709 (0.684, 0.773)
	Medium optic disc	879	321	0.486 (0.466, 0.506)	0.1802	0.506 (0.000, 0.805)	0.000 (0.000, 0.000)	0.064 (0.000, 0.206)	0.736 (0.715, 0.759)	0.782 (0.769, 0.805)
	Large optic disc	879	255	0.550 (0.527, 0.572)	0.1844	0.590 (0.000, 0.821)	0.000 (0.000, 0.000)	0.102 (0.000, 0.235)	0.765 (0.741, 0.779)	0.797 (0.780, 0.821)
ONH: C/D Horizontal	Small optic disc	879	284	0.354 (0.331, 0.376)	0.1919	0.396 (0.000, 0.731)	0.000 (0.000, 0.000)	0.000 (0.000, 0.000)	0.612 (0.598, 0.643)	0.683 (0.644, 0.731)
	Medium optic disc	879	321	0.462 (0.443, 0.482)	0.1780	0.493 (0.000, 0.808)	0.000 (0.000, 0.000)	0.000 (0.000, 0.171)	0.694 (0.685, 0.707)	0.725 (0.711, 0.808)
	Large optic disc	879	255	0.531 (0.508, 0.554)	0.1889	0.572 (0.000, 0.888)	0.000 (0.000, 0.000)	0.102 (0.000, 0.206)	0.779 (0.751, 0.803)	0.835 (0.805, 0.888)
ONH: C/D Area	Small optic disc	879	284	0.171 (0.156, 0.185)	0.1246	0.169 (0.000, 0.513)	0.000 (0.000, 0.000)	0.000 (0.000, 0.000)	0.378 (0.369, 0.424)	0.494 (0.426, 0.513)
	Medium optic disc	879	321	0.257 (0.241, 0.273)	0.1455	0.256 (0.000, 0.608)	0.000 (0.000, 0.000)	0.002 (0.000, 0.037)	0.501 (0.489, 0.517)	0.550 (0.540, 0.608)
	Large optic disc	879	255	0.327 (0.307, 0.347)	0.1624	0.331 (0.000, 0.736)	0.000 (0.000, 0.000)	0.011 (0.000, 0.042)	0.581 (0.556, 0.603)	0.623 (0.603, 0.736)
ONH: Rim Area	Small optic disc	879	284	1.270 (1.246, 1.295)	0.2102	1.259 (0.689, 1.758)	0.814 (0.689, 0.842)	0.933 (0.864, 0.971)	1.617 (1.608, 1.706)	1.738 (1.715, 1.758)
	Medium optic disc	879	321	1.441 (1.410, 1.473)	0.2848	1.457 (0.704, 2.148)	0.870 (0.704, 0.906)	0.970 (0.921, 1.025)	1.915 (1.858, 1.998)	2.037 (2.019, 2.148)
	Large optic disc	879	255	1.633 (1.585, 1.681)	0.3880	1.610 (0.690, 2.587)	0.924 (0.690, 0.989)	1.040 (1.000, 1.092)	2.358 (2.274, 2.399)	2.545 (2.404, 2.587)

8. Conclusion

The existing and updated P200TE devices have the same intended use, technological characteristics and principles of operation, and similar indications. Additionally the updated P200TE incorporates the Reference Database functionality of the iVue.

Minor differences in Reference Database implementation do not present different questions of safety or effectiveness than the predicate devices as no novel technological principles or applications are introduced. Color-coding and covariate selection are in line with the iVue and functionality has been demonstrated clinically. Thus, the P200TE is substantially equivalent to the stated predicates.